

### **REMARKS**

This responds to the Office Action dated May 25, 2006. Claims 1, 3-5, 15-18, 25, 33, and 37 are amended. Claim 2 is cancelled. No claims are added. As a result, claims 1 and 3-39 are now pending in this patent application.

#### **§112 Rejection of the Claims**

Claims 3-5, 16-18 were rejected under 35 U.S.C. § 112, second paragraph for indefiniteness for lack of antecedent basis for the recitation of particular protocols (i.e. Transport Control Protocol, User Datagram Protocol, Transport Control Protocol for transaction). Applicant has amended such claims to change “the” to “a” to remedy the lack of antecedent basis. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Claim 33 was rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness for a typographical error. Applicant has amended claim 33 in accordance with the Examiner’s previous interpretation of the same. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of this claim.

#### **§102 Rejection of the Claims**

Claims 1-2, 13-15, 23-25 and 32 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lebel et al., (U.S. 2002/0049480). Applicant respectfully traverses.

Applicant cannot find in the cited portions of the cited reference any disclosure of applying header data to each packet, wherein the header data provides transport control information that actually controls the reconstruction of the data from the data packets. Indeed, this shortcoming of the cited reference is apparently recognized in the Office Action, which only goes so far as to assert that the cited references teaches that the preamble is capable of providing assistance to an external device in “deciphering” data, and not actually “reconstructing” the data. (See Office Action ¶ 5 (citing Lebel U.S. 2002/0049480 ¶ 301.) The relied-upon portion of the cited reference merely states:

The preamble, whether of the standard pattern or the attention pattern, is used so that the RF reception hardware can establish bit synchronization (i.e. bit boundary

recognition) of the incoming data. However, the attention preamble is further used to get and hold the receiver's attention for a defined period of time. As long as the attention preamble is being received, the receiver's hardware will stay on and continue tracking the signal in anticipation of an incoming message.

(Lebel U.S. 2002/0049480 ¶ 301.) As seen from the above quotation, however, this falls considerably short of actually controlling "reconstructing" data from the data packets, even if it could arguably be read as providing assistance to an external device in "deciphering" data, as asserted by the Office Action.

Among other things, Applicant's transport control information allows reconstruction of the data from the data packets. Such transport control information can be used, for example, to determine the position of data from a particular packet, within the data being reconstructed from other packets, as presently recited or incorporated in these claims, and which is entirely absent from the cited portions of the cited reference. For example, if a packet were dropped and retransmitted, data from that re-transmitted packet could be re-inserted into the proper position in the reconstructed data stream by using the transport control information.

Applicant has amended claim 1 to overcome the rejection by, among other things, including certain language previously presented in claim 2, which clarifies that reconstruction of the data from the data packets permits use of the header data to determine the position of data from the packet within the data from other packets being reconstructed. Therefore, Applicant also responds to the Office Action's specific contentions regarding claim 2. The Office Action stated:

In regards to claim 2, Examiner takes the position that Lebel et al. teaches of an external device that receives data packets from the internal device (see for example paragraph 298) and teaches the use of an op code, a bolus number and an error checking code, all of which can be analyzed by the system and provides information as to the position of the data (see for example paragraphs 308, 309 and 310.)

(Office Action ¶ 5.) However, the cited portions of the cited reference apparently fail to describe a header with transport control information that permits reconstruction of the data from the data packets such as by using the header data to determine the position of data from the packet within the data from other packets being reconstructed. For example, the present patent specification teaches:

Such transport control information may provide one or more various pieces of information that is used to reconstruct application data from the packets. . . . Packet sequence information may be specified where protocols are used that allow packets to be communicated out of sequence.

(Application at page 9, lines 26-30.) By contrast, Lebel's "op-code" apparently merely dictates the number of data bytes within a particular message. (See Lebel U.S. 2002/0049480 ¶ 308.) Moreover, Lebel's bolus number cannot even be considered to be a header, because Lebel clearly teaches that the bolus number is included within the "data portion of the message," not the header. (See Lebel U.S. 2002/0049480 ¶ 309.) Lebel's bolus number apparently merely reflects independent counters "incremented by both the implantable device and external communication device," to reflect how many drug delivery boluses have occurred so as to avoid triggering multiple boluses of drug delivery by the implantable device in response to duplicate bolus requests by the external device. (See Lebel U.S. 2002/0049480 ¶ 309.) Moreover, because such bolus numbers apparently only pertain to "some messages dealing with drug delivery," rather than to all data messages, Applicant respectfully submits that it would be impossible to use the bolus number to control reconstruction of data in a way that permits determining the position of data from the packet within the data from other packets being reconstructed, since such other packets being reconstructed may not include a bolus number, or may be duplicate packets that include the same bolus number. Furthermore, Lebel's error checking code also fails to constitute a header with transport control information that permits reconstruction of the data from the data packets such as by using the header data to determine the position of data from the packet within the data from other packets being reconstructed. Instead, Lebel's error checking code apparently merely pertains to a cyclic redundancy code (CRC) that can detect an error in data transmission. (See Lebel U.S. 2002/0049480 ¶ 310.)

In sum, because Lebel U.S. 2002/0049480 apparently fails to disclose all elements recited or incorporated in claims 1-2, 13-15, 23-25 and 32, for the reasons discussed above, Applicant respectfully submits that no *prima facie* case of anticipation presently exists with respect to these claims. Accordingly, Applicant respectfully requests withdrawal of this rejection of these claims.

§102/103 Rejection of the Claims

Claims 3-5, 16-18, 26-28 were rejected under 35 U.S.C. 102(b) as being anticipated by Lebel et al., (U.S. 2002/0049480) or in the alternative claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel et al., (U.S. 2002/0049480) as applied to claims 1-2, 13-15, 23-25 and 32 above. Applicant respectfully traverses.

Applicant cannot find in the cited portion of the cited reference any disclosure of transport control information that corresponds to the Transport Control Protocol (TCP), the User Datagram Protocol (UDP), or the TCP for transactions (T/TCP) protocol, as similarly recited in these claims. Indeed, the Office Action admits that such language is not expressly present in the cited reference, relying instead on an argument of inherency. (*See* Office Action ¶6.) Applicant respectfully disagrees with this assertion. Applicant respectfully submits that the Office Action has not established a *prima facie* case of inherency because, as recited in MPEP § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art," citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). However, the Office Action merely states:

Examiner takes the position that the teachings of Lebel et al. are inherently capable of performing the limitations of claims 3-5 since at least one protocol is necessarily needed to carry out the transmission of data, and thus the teachings of Lebel et al. anticipate the limitations of claims 3-5.

(Office Action ¶ 6.) Applicant respectfully disagrees. The fact that "at least one protocol is necessarily needed to carry out the transmission of data" does not, by itself, dictate the necessity of the particular protocols recited in these claims. Accordingly, Applicant respectfully submits that claims 3-5, 16-18, 26-28 cannot be properly rejected under a theory of inherency using Lebel U.S. 2002/0049480. Therefore, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Alternatively, the Office Action has rejected such claims under the theory of obviousness. (*See* Office Action ¶6.) The Office Action asserts:

Examiner takes the position that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Lebel et al. to include various types of standard protocol as claimed by Applicant, since these

types of protocol are standard and well known in the art, as these teachings are admitted prior art by Applicant (see Applicant's Specification paragraph 29.)

(Office Action ¶6.) Applicant respectfully disagrees. First, as discussed above, there is no express disclosure, teaching, or suggestion of the particular recited protocols in Lebel U.S. 2002/0049480. Therefore, Applicant respectfully submits that no *prima facie* case of obviousness exists with respect to claims 3-5, 16-18, 26-28. Second, Applicant expressly objects to any characterization of Applicant's own disclosure as "admitted prior art," or as somehow establishing the elements missing from Lebel. The cited portion of Applicant's own disclosure merely states:

The transport layer 308 is implemented by information exchange instructions that are executed by the processor 202. The transport layer 308 may provide a standard transport layer protocol such as the transmission control protocol ("TCP"), the TCP for transactions protocol ("T/TCP"), the User Datagram Protocol ("UDP") or other known transport layer protocols that provide either streaming or record based exchange of application data. Other transport control protocols that may be utilized include ATM Adaptation Layer protocol and Service Specific Connection Oriented Protocol. Transport control information is included in a header for each outgoing packet to instruct a processor of an external device implementing the same transport protocol as to how the packets are used to reconstruct the application data. Similarly, transport control information is included in a header for each incoming packet to instruct the processor 202 implementing transport layer 308 as to how the incoming packets should be used to reconstruct application data.

(Application (U.S. Patent Publication 20050027329 ¶ 29.) Although standards exist for such specific protocols in the external-only computer network communication arts, there is no objective evidence of record of the use of any of the particularly recited protocols in communicating between an implantable medical device and an external device, as recited or incorporated in these claims. Instead, Applicant's specification expressly explains why such standardized protocols are generally not used for communication between implantable and external devices:

Conventionally, the implantable pulse generator communicates under the control of an application program. The external device in communication with the implantable pulse generator utilizes a complimentary application program so that there is a compatible exchange of data between the two devices. Thus, a standardized communication protocol is not utilized since the communication is directly between the application programs of the two devices. However, because

there is no standardized form of communication, the implantable pulse generator is limited in its ability to communicate with a variety of devices and application programs.

(Application (U.S. Patent Publication 20050027329 ¶ 3.)

In sum, Applicant respectfully submits that there is no *prima facie* case of obviousness for the claims 3-5, 16-18, 26-28. Accordingly, Applicant respectfully requests withdrawal of this rejection of these claims.

### §103 Rejection of the Claims

1. Claims 6-12, 19-22, and 29-31 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lebel et al., (U.S. 2002/0049480) as applied to claims 1-2, 13-15, 23-25 and 32 above, and further in view of Lee (U.S. 2001/0031997). Applicant respectfully traverses this rejection of these dependent claims on the grounds that no *prima facie* case of obviousness presently exists with respect to these claims for the reasons discussed above with respect to the § 102 rejection of their base independent claims, because Applicant cannot find anything in the cited portions of Lee that provides the elements of the present claims that Applicant has already established as being absent from Lebel. Nonetheless, Applicant responds below to a few additional points made in this § 103 rejection of these claims.

First, the Office Action states that

In regards to claims 6-7, 12, 19, 22 and 29 the Lee reference teaches that the interface medical device (116) could be placed outside the patient, which Examiner interprets to also mean that the interface medical device could alternatively be placed inside the patient (see for example paragraph 28), in a position similar to the implanted medical device (112), which are both part of an implantable medical device network system.

(Office Action ¶ 7.) Applicant respectfully strongly disagrees with this assertion, which Applicant respectfully submits amounts to an unreasonable interpretation of the Lee reference. The Office Action is attempting to use a teaching of the Lee reference (i.e., an external device that may be positioned outside the patient) to establish exactly the opposite! However, nothing in Lee expressly discloses, teaches, or suggests placing external device 116 inside a patient—and this component is in fact referred to as an “external” device whose whole purpose is to interface to an “implantable” medical device 112. An objective view of the Office Action’s argument

would recognize that the Office Action is attempting to rely on a theory of inherency, albeit without expressly stating it as such. However, Applicant respectfully submits that the Office Action has not established a *prima facie* case of inherency because, as recited in MPEP § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art," citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). The Office Action's proposed interpretation of an "implantable" external interface medical unit 116 does not necessarily flow from the teachings of Lee, since Lee expressly teaches that interface medical unit 116 is external, and to make it internal would in fact destroy the stated purpose of the external interface medical unit 116, which is to communicate with the implantable medical device 116.

The Office Action additionally asserts:

Examiner further takes the position that it would have been obvious to one having ordinary skill in the art to modify the system as taught by Lebel et al. to include in each packet information regarding network routing information and to combine these teachings into a single implanted device, for enhancing data transmission and accessibility, and for increasing implantation feasibility.

(Office Action ¶ 7.) Applicant respectfully notes that the combination of Lebel and Lee fails to provide any objective evidence of applying routing or other recited information "at the implantable pulse generator device," as similarly incorporated in these claims from their independent base claims 1 and 15. Instead, the Office Action's conclusory assertion appears to amount to nothing more than hindsight reconstruction derived from the Applicant's own disclosure.

Applicant also expressly objects to any characterization of Applicant's own disclosure as "admitted prior art," or as somehow establishing the elements missing from Lebel and/or Lee. As discussed above, although standards exist for such specific protocols in the external-only computer network communication arts, there is no objective evidence of record of the use of any of the particularly recited protocols in communicating between an implantable medical device and an external device, as recited or incorporated in these claims. As discussed above, Applicant's specification expressly explains why such standardized protocols are generally not

used for communication between implantable and external devices. (See Application (U.S. Patent Publication 20050027329 ¶ 3.)

In view of the above, Applicant respectfully requests withdrawal of this § 103 rejection of these claims.

2. Claims 33-39 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lebel et al., (U.S. 2002/0049480) as applied to claims 1-2, 13-15, 23-25 and 32 above, in view of Nappholz et al., (U.S. Patent No. 5,720,770). Applicant respectfully traverses this rejection.

Applicant cannot find in the cited portions of the cited references any disclosure, teaching, or suggestion of establishing a first transport layer connection between the data network and the repeater over the wired connection, and establishing a different second transport layer connection between the repeater and the implantable pulse generator over the wireless connection, as presently similarly recited or incorporated in these claims. In fact, the Office Action admits that this is not present in Lebel et al. and/or Nappholz. Instead, the Office Action states:

Examiner takes the position that the Nappholz et al. reference inherently teaches the ability to establish a first transport layer between the data network and the repeater and a second transport layer connection between the repeater [and the] implantable pulse generator, since this would be required for the transmission of data over both a wired connection and wireless connection respectively.

(Office Action ¶8.) Applicant respectfully disagrees. The Office Action's position appears to impermissibly ignore the words "transport layer" that modify the term connection, since Nappholz apparently merely shows different (e.g., wired and wireless) connections between the IMD and the repeater, and between the repeater and the data network. Applicant respectfully submits that one of ordinary skill in the art would recognize the words "transport layer" modifying "connection" render the claimed "transport layer connections" within a particular communication protocol to be different than the physical wireless and wired connections of Nappholz.

Indeed, the present patent application provides an example of using the same transport layer connection for both the wireless and wired connections, by way of a contrast to the claimed



different transport layer connections for the wired and wireless connections. The present patent application explains:

As shown in FIG. 6, this system addresses these issues by providing two transport layer connections, one for each subnetwork that is present. The first transport layer connection is established between the pulse generator 604 and the repeater 610 for the wireless subnetwork. Additionally, the second transport layer connection is established between the repeater 610 and the data network 612 for the wired subnetwork. Because the repeater 610 acts as the bridge between the two subnetworks, the repeater 610 must perform bridging operations, discussed below with reference to FIG. 7, between the two transport layer connections rather than perform simple router functions like the repeater 114 of FIG. 1.

(Application (U.S. Patent Publication 20050027329 ¶ 48.) Thus, the present patent application describes two examples: FIG. 1 includes both wired and wireless physical connections, but need not use different transport layer connections for the wired and wireless connections; FIG. 6 also includes both wired and wireless physical connections, but provides different transport layer connections for the wired and wireless connections. This vitiates the Office Action's argument that wired and wireless physical connections inherently provide different transport layer connections within a particular communication protocol. Applicant respectfully submits that the Office Action has not established a *prima facie* case of inherency because, as recited in MPEP § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art," citing Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original). As evidenced by the examples in the present patent application, a characteristic of using two different transport layer protocols for the wired and wireless physical connections is not necessary, although it can be beneficial. The present patent application also speaks at great length to a problem that is solved by using two different transport layer protocols for the wired and wireless physical connections. The present Application states:

The system of FIG. 6 addresses issues caused by utilizing certain standard transport protocols such as TCP when transmitting data over a wireless link between a data network and a pulse generator, such as through a repeater. While the lower layers of the stack may deal with re-tries of communication without causing a breakdown in the communication system, the transport layer of the

pulse generator 604 or data network 612 may see the delay as indicating lost packets and then begin to increase the retransmission of packets exponentially up to a predefined maximum value. There is a re-transmission timeout for each time a packet is retransmitted, and this timeout also increases exponentially. After several consecutive re-transmission timeouts for sending packets, the transport layer may consider the link broken such that the sending side drops the connection entirely. Furthermore, because the transport layer does not reset the re-transmission timeout value upon a link being re-established, this value can grow to a large value that causes lengthy delays before a packet can be re-sent even though the link to send over may be available during the lengthy delay.

As shown in FIG. 6, this system addresses these issues by providing two transport layer connections, one for each subnetwork that is present. The first transport layer connection is established between the pulse generator 604 and the repeater 610 for the wireless subnetwork. Additionally, the second transport layer connection is established between the repeater 610 and the data network 612 for the wired subnetwork. Because the repeater 610 acts as the bridge between the two subnetworks, the repeater 610 must perform bridging operations, discussed below with reference to FIG. 7, between the two transport layer connections rather than perform simple router functions like the repeater 114 of FIG. 1.

Thus, the repeater 610 maintains separate transport layer connections to avoid the issues above. The transport layer connection between the repeater 610 and the data network 612 is a reliable wired connection so that neither device experiences enough re-transmission to drop the connection nor establish a lengthy re-transmission timeout. However, this transport layer connection continues to use and benefit from the re-transmission timeout as well as other timeouts of a transport protocol such as TCP. The transport layer connection between the repeater 610 and the pulse generator 604 utilizes a transport layer protocol such as TCP but with this transport layer protocol configured to handle re-transmission timeouts differently. For example, the re-transmission timeout may be set to a relatively small maximum so that there are not significant delays once it reaches its maximum. Alternatively or in addition to this configuration to the transport layer connection, the re-transmission timer and other timers of the transport layer protocol may be reset each time the link is lost so that the maximum re-transmission timeout does not continue upon the link being re-established.

(Application (U.S. Patent Publication 20050027329 ¶¶ 47-49.))

The Office Action also states:

Further, it is inherent in the system as taught by Nappholz et al. that the system is capable of sending data with first transport control header information from the

data network to the repeater and further sending the data with the second transport control header information from the repeater to the implantable pulse generator.

(Office Action ¶ 8.) Applicant respectfully disagrees because, as explained above, Nappholz apparently fails to disclose, teach, or even suggest using different transport layer connections, rather than merely using different (e.g., wired and wireless) physical layer connections, nor is there any objective evidence of record that Nappholz actually describes using first transport control header information over the first transport layer connection, and using second transport control header information over the second transport layer connection.

The Office Action further asserts:

In regards to claim 35 and 38-39, Examiner takes the position that it is inherent in both the Lebel et al. and Nappholz et al. systems that a transport control protocol would be necessary to allow proper transmission of data, or in the alternative would be an obvious modification to the Lebel et al. reference.

(Office Action ¶ 8.) Applicant respectfully disagrees. Again, these claims include language directed toward different first and second transport layer connections, rather than different physical (e.g., wired and wireless) connections. Applicant has provided at least one example in which this need not be the case, thereby vitiating the inherency argument of the Office Action.

The Office Action further states:

Examiner further takes the position that it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a longer re-transmission time timeout for the connection between the repeater and the implantable device, than for the data network and the repeater, since it is well known in the art that a transmission over a shorter distance (i.e. close proximity) requires less time than does a transmission over a longer distance (i.e., cellular connection).

(Office Action ¶ 8.) Applicant respectfully disagrees with the basis of this assertion. Even if a transmission over a longer distance takes longer than a transmission over a shorter distance, by itself, that would not necessarily lead one of ordinary skill in the art to select the transmission time-outs as claimed, since there is no objective evidence of record that the difference in distances of such communication would be so great as to cause any problem for the communication. Instead, the present patent application expressly points out the present

inventors' recognition of the problem of how lower layers of the stack may deal with re-tries of communication, and how the different re-transmission time-outs can avoid such problems:

The system of FIG. 6 addresses issues caused by utilizing certain standard transport protocols such as TCP when transmitting data over a wireless link between a data network and a pulse generator, such as through a repeater. While the lower layers of the stack may deal with re-tries of communication without causing a breakdown in the communication system, the transport layer of the pulse generator 604 or data network 612 may see the delay as indicating lost packets and then begin to increase the retransmission of packets exponentially up to a predefined maximum value. There is a re-transmission timeout for each time a packet is retransmitted, and this timeout also increases exponentially. After several consecutive re-transmission timeouts for sending packets, the transport layer may consider the link broken such that the sending side drops the connection entirely. Furthermore, because the transport layer does not reset the re-transmission timeout value upon a link being re-established, this value can grow to a large value that causes lengthy delays before a packet can be re-sent even though the link to send over may be available during the lengthy delay.

(Application (U.S. Patent Publication 20050027329 ¶¶ 47.))

In view of the above, Applicant respectfully submits that there is no *prima facie* case of obviousness of claims 33-39. Accordingly, Applicant respectfully requests withdrawal of this rejection of these claims.

*Reservation of Rights; References Not Relied Upon*

Applicant need not address any references that were made of record but not relied upon as a basis of rejection. Applicant does not admit that such references are prior art or applicable against the present claims, and Applicant reserves the right to address such references if they are subsequently made a basis of rejection. Applicant reserves the right to swear behind any references which are cited in a rejection under 35 U.S.C. 102(a), 102(e), 103/102(a), and 103/102(e), such as provided under 37 C.F.R. § 1.131 or otherwise. Statements distinguishing the claimed subject matter over the cited documents are not to be interpreted as admissions that the documents used as references are prior art.

**CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.


Respectfully submitted,

PAUL HOLMQUIST ET AL.

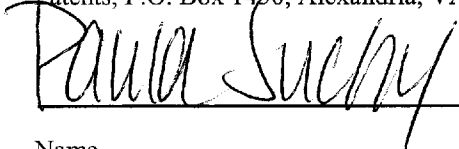
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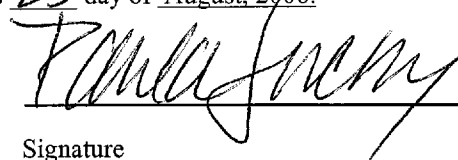
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